Customer No. 23932

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:	Atty. Docket No.: 47168-00035USC1
Richard J. Lazzara Thomas S. Heylmun Keith D. Beaty	Examiner: Paul Prebilic
	Group Art Unit: 3738
Application No.: 09/237,605	
Filed: January 25, 1999	
For: Infection-Blocking Dental Implant	

DECLARATION OF PRABHU GUBBI

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Prabhu Gubbi, declare that:

A. I reside at 4445 SW Oakhaven Lane, Palm City, FL 34990.

B. I have degrees in Mechanical Engineering and Foundry Engineering from Bangalore University, India. I also have a Ph.D. degree in Materials Engineering from Auburn University. Since receiving my Ph.D., I have been employed as an engineer with several corporations where I have worked as a material scientist. Currently, I am a materials scientist with Implant Innovations, Inc ("***3i***").

C. In the course of my work at ***3i***, I have examined numerous surfaces of objects used in dental implantology. One of the machines that I use to examine these surfaces is a Scanning Electron Microscope (SEM). The machine that I use is made by Aspex Instruments LLC and its Model number is PSEM II. This machine is about 4 years old.

D. Within the past several months, I have reviewed several dental implant surfaces from other manufacturers. I understood that the purpose of my review was to develop a summary of competitive implant surfaces that were to be submitted to the U.S. Patent & Trademark Office in connection with the present patent application, which is assigned to ***3i***.

E. When developing each implant sheet, I developed a picture of the package in which the implant came (assuming it had a package), an SEM picture at 25X of the implant, and an SEM picture at 2000X to see the microstructure on the implant surface.

F. I have tried to determine the manufacturing date of each implant as accurately as possible based on the information provided by implant manufacturers on the package. Most of the manufacturers have placed either a "sterilization" date or a "use before" date (i.e., "expiration" date) on the package. For those manufacturers that provide only a "use before" or "expiration" date, it was assumed that the implant was manufactured at least two years earlier. Some manufactures provide a "lot number" which suggests a manufacturing date in its code. Further, because it is my understanding that implant manufacturers have provided sterile implants to clinicians since at least 1990, any non-sterile implants were assumed to be from the 1980's.

G. Implants in 35 through 61 are from lawsuit civil action #91-C-4632, filed in the Northern District of Illinois related to US Patent #4,330,891, which was concluded in 1998. These implants are believed to have been made in the 1970s, 1980s or early 1990s. The extent, if any, of the sales or other public disclosure of these implants is currently not known.

H. The enclosed report contains one sheet on each of the following 61 implants.

1. Institut-Straumann AG - titanium plasma sprayed hollow cylindrical implant in an unsterilized package believed to be from the 1980's

2. Institut-Straumann AG - titanium plasma sprayed hollow cylindrical implant in an unsterilized package believed to be from the late 1980's

3. Calcitek - HA-coated "Integral Omniloc" implant believed to be from 1995

4. Calcitek - HA-coated "Integral Omniloc" implant believed to be from 1990

5. Imtec - HA-coated implant distributed by Osteomed Inc. believed to be from 1994

6 Interpore - HA-coated implant believed to be from 1989

7. Interpore - titanium plasma sprayed implant believed to be from 1993

8. Minimatic - titanium plasma sprayed implant believed to be from 1993

9. Stryker - HA-coated implant believed to be from 1987

10. The "O" Company - push-in implant with blasted surface believed to be from 1994

11. Impla-Med - HA-coated implant believed to be before 1992

12. Collagen Biomedical - HA-coated implant believed to be from 1991

13. Steri-Oss - HA-coated implant believed to be from 1990

14. Friedrichsfeld - titanium plasma sprayed implant believed to be distributed in Germany in 1991

15. Lifecore Biomedical - titanium plasma sprayed implant believed to be from 1995

16. Stryker - titanium plasma sprayed implant believed to be from 1992

17. Mathys - threaded implant believed to be from 1992

18. Nobelpharma - machined implant believed to be from 1991

19. Nobelpharma - machined implant believed to be from 1987

20. Miter, Inc. - blade-style implant with blasted surface believed to be from 1986

21. Miter, Inc. - blade-style implant with blasted + etched surface believed to be from 1987

22. Astra Dental - machined implant believed to be before 1996

23. Calcitek - HA-coated "Integral SD" implant believed to be from 1988

24. Lifecore Biomedical - HA-coated implant believed to be from 1995

25. Lifecore Biomedical - machined implant believed to be from 1995

26. Collagen Biomedical - machined implant believed to be from 1990

27. Institut Straumann - titanium plasma sprayed hollow screw implant in an unsterilized package believed to be from the 1980's

28. Institut Straumann - titanium plasma sprayed screw implant in an unsterilized package believed to be from the 1980's

29. Astra Tech - screw implant with blasted surface believed to be before 1997

30. Core-Vent - screw implant with blasted surface believed to be from 1996

31. Straumann - titanium plasma sprayed implant believed to be before 1996

32. Institut Straumann - titanium plasma sprayed implant believed to be before 1995

33. Dentsply Core-Vent - HA-coated implant believed to be before 1996

34. Dentsply Core-Vent - machined implant believed to be before 1996

35. Cherchev Implant – implant appears to have blasted surface

36. Samson Titanium Screw – implant appears to have machined surface

37. Oratronics Spiral – implant appears to have a slightly roughened surface

38. Oratronics Blade – implant appears to have a slightly roughened surface

39. Synthodont – implant appears to have a blasted surface

40. Vitradent – implant appears to have a slightly roughened surface

41. Zimmer Mandibular Staple – implant appears to have blasted surface

42. MI-150-TI – implant appears to have machined surface

43. Ti 1968-70 – implant appears to have a slightly roughened surface

44. Cast Vitallium Surgical – implant appears to have a blasted surface

45. Park Dental – implant appears to have a slightly roughened surface

46. Babbush Implants – implant appears to have blasted surface

47. Oratronics – implant appears to have a slightly roughened surface

48. Swingos – implant appears to have a slightly roughened surface

49. Konkoly – implant appears to have a slightly roughened surface

50. Sulzer Protusil – implant appears to have a titanium plasma sprayed surface

51. IRC Curved – implant appears to have a slightly roughened surface

52. Oratronics – implant appears to have a slightly roughened surface

53. Hamilton – implant appears to have a slightly roughened surface

54. Barton Partial – implant appears to have blasted surface

55. Arenson – implant appears to have blasted surface

56. IRC Clinical Retrieval – implant appears to have a slightly roughened surface

57. Park Dental – implant appears to have blasted surface

58. Oratronics – implant appears to have a slightly roughened surface

59. Interplant – implant appears to have blasted surface

60. Subperiosteal – implant appears to have a slightly roughened surface

61. Continuous Blade – implant appears to have a machined surface

Date: 11-02-2001

Prabhu Gubbi